TESTIMONY OF ANGELA TREPANIER, CGC, Assistant Professor, Director Genetic Counseling Graduate Program, Wayne State University, Past President National Society of Genetic Counselors
before the
STATE OF MICHIGAN HOUSE OF REPRESENTATIVES
HEALTH POLICY COMMITTEE

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Madam Chairman Haines, Vice-Chairpersons Callton and Liss, and distinguished Members; I am Angela Trepanier, a Certified Genetic Counselor, from Detroit. I am a faculty member and director of the genetic counseling graduate program at the Wayne State University School of Medicine. I am also a member of the Michigan Association of Genetic Counselors, past president of the National Society of Genetic Counselors (NSGC), and a current board member the National Coalition of Health Professional Education in Genetics. On behalf of Michigan Genetic Counselors, we want to thank Representative Callton and the many of you on this committee that have introduced and cosponsored House Bill 4756. I appreciate the opportunity to testify in favor of this important legislation that would provide licensure for certified genetic counselors in Michigan.

Genetic counselors are healthcare providers with significant training and expertise in molecular biology, medical genetics and psychosocial counseling, obtained through a 2 year Masters level program. Most students enter the field from a variety of disciplines including biology, genetics, psychology, and public health. There are 33 accredited graduate programs in the United States and Canada including two in Michigan, housed at the University of Michigan and at Wayne State University.

Genetic counselors are part of a health care team providing information and support to individuals and families concerned about risk of genetic disorders. Genetic counselors:

- Collect and interpret family and medical histories,
- Identify individuals and families at risk of genetic conditions
- Explain inheritance and natural history
- Quantify chance of occurrence and recurrence
- Review available testing options
- Discuss management, prevention, and research opportunities
- Serve as patient advocates and refer individuals and families to community or state support services as appropriate

Genetic counselors are employed in a wide range of clinical care, academic, laboratory, research, and biotechnology settings. Within Michigan there are over 60 genetic counselors, most of whom provide direct patient care in a variety of specialties including but not limited to Obstetrics, Oncology, Pediatrics,

Neurology, Cardiology, Ophthalmology, and preimplantation genetic diagnosis. There are also several genetic counselors working for the Michigan Department of Community Health on public health genomics programs including newborn screening follow up and chronic disease genomics. In fact, Michigan is a model state in terms of advancing public health genomics initiatives.

HB 4756 is extremely important as the bill would help protect the public from potential harms that may result from this occupation remaining unregulated. Harms caused by untrained individuals attempting to provide genetic counseling include:

- Misinformation regarding genetic risk or lack of risk;
- Misunderstanding of the implications of genetic information such as family history or test results, which can lead to:
    - unnecessary medical treatment and/or surgery
    - lack of prevention or disease monitoring strategies
    - irreversible management decisions
    - Avoidable fear, anxiety and guilt
- Inappropriately undertaking costly genetic testing

The availability of genetic and genomic testing services is growing rapidly.Today, according to the GeneTests, a federally funding genetic testing resource, 599 laboratories are offering genetic testing for 2338 different diseases. This represents a 23% increase from 2009 (see chart below). Not only are there more tests, but the complexity of testing is changing. Experiences with full genome sequencing, which is currently being done under research protocols, has shown us that there are a myriad of issues that have to be considered when you look at all of a person's genetic information. For instance, what do you do when you incidentally identify risk for an adult onset condition in a child having full genome sequencing to identify the cause of his multiple birth defects? Or, what do you do when a clinically available SNP-based microarray test that is done to identify the cause of mental retardation also identifies that the child is the product of an incestuous relationship?

To quote the Secretary's Advisory Committee on Genetics, Health and Society's 2011 Executive Summary on Genetics Education and Training,

"The growing integration of genetics and genomics findings into mainstream medicine and the emergence of direct-to-consumer genetic testing amplify the need for understanding risk assessment, multi-gene and genomic diagnostics, genetic-based treatment, and effective strategies in communicating genetic test results to patients and consumers. However, health care professionals, the public health workforce, patients and consumers are challenged to keep pace with this dynamic and rapidly evolving field."

Genetic counselors, with their specialized training, are ideally suited to work hand-in hand with physicians and health care providers to ensure the delivery of high quality, up-to-date genomics services and to make sure that the patients utilizing these services are adequately informed. As such, they are key players in appropriately integrating genomics into health care and also in avoiding the significant harm that can occur when genetic risk is not identified or when a patient is not properly counseled before genetic testing is done.

In addition, genetic counselors provide services that are cost-effectiveness. We assure tests are utilized appropriately. Many health care providers often request unnecessary testing or incorrect tests increasing the cost of health care. Non-genetics health care professionals have also been demonstrated to underestimate patients' genetic risks because of ineffective family history evaluation. For many genetic conditions, 50% of first degree relatives (siblings, parents, children) of a person with a genetic mutation will also carry a mutation and are at risk to manifest the disease or transmit the mutation. Identifying those who carry a mutation offers the opportunity for preventive screening and treatment, thus lowering the chance of disease manifestations. Moreover, identifying those family members who do *not* carry a mutation eliminates the need for expensive clinical follow-up.

Let me give you an example from my own practice. A 45-year old woman and her 75-year old father presented for genetic counseling because of a family history of breast and ovarian cancer. One of the father's sisters had died of ovarian cancer when she was in her 40's. This woman's daughter had recently been diagnosed with ovarian cancer and had pursued genetic testing that revealed she had a mutation in the BRCA2 breast ovarian cancer gene. The father also had another sister with breast cancer, diagnosed when she was in her 30's. My patient and her two sisters had been told that since the family history was on her father' side of the family, they were not at risk. This is not true. Mutations in the hereditary breast ovarian cancer genes, BRCA1 and BRCA 2, which cause a high risk of developing early onset breast cancer and ovarian cancer, are passed down in dominant fashion. This means that a mutation can be passed from either the mother or the father's side. In this case, my patient's father had a 50/50 (1 in 2) chance of carrying the mutation in his side of the family. If he were found to carry the mutation, each of his daughters would also have a 50/50 chance. Women with a mutation begin screening for breast cancer at an earlier age (~25 years) using both breast MRI and mammography. Screening for ovarian cancer is also done; however, given limitations in its effectiveness, removing the ovaries after childbearing is recommended and is shown to significantly reduce the risk of developing and dying from ovarian cancer. The inaccurate risk assessment in this case had serious medical implications for this family. In addition, it contributed to psychological harm in that the family found out about their risk for the first time in the midst of their relative dying from ovarian cancer. In actuality the risk could have been identified much earlier.

In summary, genomics is changing rapidly and genetic counselors are key players in appropriately and effectively integrating genomic applications into health care. Clinicians and patients need to know that the genetic counselors they work with/see are adequately trained and up-to-date on genomic information. We urge you to enact this legislation as it would establish requirements for the licensure of genetic counselors ensuring minimum standards for individuals in terms of academic achievement, clinical experience, and skills necessary to deliver high quality genetic counseling services. Currently in Michigan there is no legal standard for who can represent themselves as genetic counselors. As the field of medical genetics grows, there is and will continue to be a need to provide the citizens of Michigan with accurate information regarding their genetic risks and results of genetic tests. At present, there is no mechanism that assures citizens that the individual who is providing this information is qualified to do so. In a climate where direct-to-consumer genetic testing via internet companies is widely available and where the complexity of genomic tests are increasing, the citizens of Michigan need to have access to professionals who have been deemed qualified by the state to help them understand their potential genetic risks.

Additionally, there is no way for employers to assure they are hiring individuals who have the appropriate training and education to provide genetic counseling services or that would prohibit unskilled individuals from using the title of genetic counselor.

This is also important to Michigan as the field of genetic counseling is growing rapidly; membership to the NSGC has grown by over 50% in the past 6 years and the number of genetic counseling training programs in the U.S. has increased significantly. As I previously stated, there are currently 2 training programs in Michigan and we graduate approximately 12 students per year. Currently, about 45% of my graduates seek employment in Michigan and make up almost a quarter of the current workforce. Because other states are increasingly offering the ability to become licensed, students may not apply to our programs and those that do may seek employment outside of Michigan in states with licensure. We may also have a hard time attracting new graduates from outside the state to practice here or may not get the same caliber of graduates as states with licensure get. These circumstances place our state at a disadvantage compared to others and it could result in a loss of revenue and tax base. In addition, it could decrease patient access to the specialized health care services that genetic counselors provide.

In conclusion, the Michigan Association of Genetic Counselors is hopeful that the committee will work with Representative Callton and the other co-sponsors to enact genetic counseling licensure that will ensure the people of Michigan receive quality genetic counselor services. We believe the people of Michigan will

be well served. We thank the Madam Chairman and this committee for your attention to this important issue, and we offer ourselves as a resource as you move forward.